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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,721	03/01/2007	Ralf Himmelreich	075422-0015	3167

20277 7590 06/09/2010

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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
06/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,721	HIMMELREICH ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed March 1, 2010. Claims 1-23 were previously pending. Applicants cancelled claims 2, 3 and 23 and amended claims 1 and 4-22. Claims 1 and 4-22 are pending and will be examined.

2. Applicants' amendments and claim cancellations overcame all of the previously presented claim rejections. This office action contains new grounds for rejection necessitated by amendment.

3. This office action contains new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-10, 14 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (U.S. Patent No. 6,310,199 B2; issued October 2001).

Regarding claim 1, Smith et al. teach a method of genomic DNA purification comprising:

a) lysing the nucleic acid source (col. 29, lines 46-52),

b) filtering the lysate through a porous matrix consisting of a material based on silica or of a silica coated material to bind the nucleic acid to the porous matrix in the absence of an alcohol and in the absence of a chaotropic salt (col. 25, lines 35-40; col. 29, lines 54-61; col. 8, lines 41-67; col. 9, lines 1-5; col. 10, lines 46-60; col. 14, lines 16-25 and 35-42),

c) eluting the nucleic acid from the porous matrix of step b) by using an aqueous buffer solution to provide isolated genomic DNA (col. 14, lines 16-25; col. 29, lines 63-65).

Regarding claims 5 and 6, Smith et al. teach blood, tissue, animal cells and bacteria (col. 1, lines 62-65; col. 7, lines 65-67; col. 23, lines 30-34; col. 29, lines 46-47).

Regarding claim 7, Smith et al. teach lysing solution which does not contain a chaotropic salt or alcohol (col. 14, lines 35-42; col. 29, lines 46-52).

Regarding claim 8, Smith et al. teach using proteinase K after cell lysis (col. 29, lines 54-55).

Regarding claims 9 and 10, Smith et al. teach silica and glass membranes (col. 8, lines 41-50; col. 10, lines 45-60).

Regarding claim 14, Smith et al. teach subsequent application of the DNA (col. 2, lines 58-59; col. 30, lines 1-5).

Regarding claim 16, Smith et al. teach centrifugation to eliminate cell debris (col. 23, lines 30-60).

Regarding claims 17 and 18, Smith et al. teach performing washes of matrix using washing buffer before eluting DNA (col. 29, lines 62-63).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,310,199 B2; issued October 2001) and Colpan (US 6,277,648 B1; cited in the previous office action).

A) The teachings of Smith et al. are presented above. They do not specifically teach genomic DNA in the size range between 10 and 50 kb or membrane filter plates or tubes.

B) Regarding claim 1, Colpan teaches a method of rapid isolation of nucleic acid, the method comprising:

a) lysing the nucleic acid source (col. 5, lines 3-5; col. 6, lines 34-36; col. 7, lines 4-6),

b) filtering the lysate through a porous matrix consisting of a material based on silica or of a silica coated material to bind the nucleic acid to the porous matrix in the absence of an alcohol and in the absence of a chaotropic salt (col. 2, lines 1-8; col. 5, lines 8-18; col. 6, lines 41-52; col. 7, lines 13-18),

c) eluting the nucleic acid from the porous matrix of step b) by using an aqueous buffer solution (col. 5, lines 21-23; col. 6, lines 57-58; col. 7, lines 29-31).

Regarding claims 1 and 4, Colpan teaches genomic DNA and size range from 1 to 50 kb (col. 1, lines 65-67).

Regarding claim 19, Colpan teaches single column filter tube (Fig. 1-6).

Regarding claim 20, Colpan teaches multi-well filter plate 9col. 4, lines 58-62).

Regarding claim 21, Colpan teaches membrane assembled in multiple layers (Fig. 1).

Regarding claim 22, Colpan teaches pore sizes being different in the different layers (col. 2, lines 49-67).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the filter matrices of Smith et al. in the arrangement suggested by Colpan. The motivation to do so is provided by Colpan is that lysed cells were applied directly to filters without the need for centrifugation and cells could be lysed directly on filters (col. 1, lines 29-46; col. 5, lines 30-60).

8. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,310,199 B2; issued October 2001).

Regarding claims 11-13, Smith et al. teach pore sizes larger than 0.6 microns (col. 10, lines 59-60), but do not specifically teach pore sizes in the range of between 0.2 and 3.2 microns.

However, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used filters with different pore sizes in the method of Smith et al. according to the size of DNA to be purified. It would have been prima facie obvious to perform routine optimization to determine optimal filter pore size, as noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific filter pore sizes was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. Patent No. 6,310,199 B2; issued October 2001) and Heid et al. (Genome Res., vol. 6, pp. 986-994, 1996).

A) Regarding claim 15, Smith et al. teach amplification of isolated DNA (col. 2, line 59), but do not specifically teach PCR or quantitative real-time PCR.

B) Heid et al. teach quantitative real-time PCR on human genomic DNA to determine a number of copies of a DNA gene (Abstract; page 987, third and fourth paragraph; page 988; page 993).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used real-time quantitative PCR of Heid et al. to analyze purified genomic DNA of Smith et al. The motivation to do so would have been that such analysis allowed for accurate quantitation of the amount of genomic DNA (see Fig. 1, for example). As stated by Heid et al. (page 991, last paragraph; page 992, first paragraph):

"The real-time PCR method offers several advantages over the other two methods currently employed (see the introduction). First, the real-time PCR method is performed in a closed-tube system and requires no post-PCR manipulation of sample. Therefore, the potential for PCR contamination in the laboratory is reduced because amplified products can be analyzed and disposed of without opening the reaction tubes. Second, this method supports the use of a normalization gene (i.e., [β-actin) for quantitative PCR or housekeeping genes for quantitative RT-PCR controls. Analysis is performed in real time during the log phase of product accumulation. Analysis during log phase permits many different genes (over a wide input target range) to be analyzed simultaneously, without concern of reaching reaction plateau at different cycles. This will make multigene analysis assays much easier to develop, because individual internal competitors will not be needed for each gene under analysis. Third, sample throughput will increase dramatically with the new method because there is no post-PCR processing time. Additionally, working in a 96-well format is highly compatible with automation technology."

10. No claims are allowed.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
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/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
June 6, 2010